

REMARKS

Claims 1-4, 6-9, 22-24, 32 and 38 are amended and claims 15, 16, 26 and 28 are cancelled herein without prejudice or disclaimer. In addition, new claim 46 is added. Claims 1-14, 17-25, 27, 29-46 are pending in the application. Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Applicant notes with appreciation that the Examiner has withdrawn the previous restriction and indicated that all of the claims 1-48 were under consideration.

Objection To Drawings:

The drawings were objected to as being informal in format and replete with markings. In response, formal drawings are submitted herewith. The formal drawings correspond to the original drawings and do not add new matter to the application. Applicant requests that the objection to the drawings be withdrawn, in view of the formal drawings submitted herewith.

Objection To Specification:

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Examiner stated that the specification does not mention the feature “wherein the outer layer provides a barrier against diffusion of carbon dioxide” as recited in claims 11, 20, and 31.

In response, it is noted that each of claims 11, 20 and 31 are part of the original application and, thus, part of the original disclosure. For better correspondence between other portions of the specification and those claims, Applicant has amended paragraph [0024] to recite that, “[i]n addition, the outer layer 12 can provide a barrier against diffusion of carbon dioxide.” Because the text added to paragraph [0024] corresponds to the text of original claims 11, 20 and 31, no new matter is added to the specification. At least by the present amendment to the specification, claims 11, 20 and 31 have corresponding antecedent disclosure in the application. Accordingly, Applicant requests that the objection to the specification be withdrawn.

Rejection Under 35 U.S.C. 102(b):

Claims 1-11, 21-34, 38, 39 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO Publication WO 03/064909 A1 to Donohue et al. (hereinafter “Donohue”). With regard to cancelled claims 26 and 28, this rejection is moot. With regard to the other listed claims, this rejection is respectfully traversed.

Independent claims 32 and 38 are amended herein and are further distinguished from the references of record, including Donohue.

For example, claim 32 recites a “tubing for conveying a fluidic media, the tubing comprising at least one layer of copolyester ether (COPE) material selected to be suitably compatible with the media, wherein the at least one layer of COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing.”

The Examiner cited Donohue as describing a co-extruded tubing having an outer layer (1) of a polyester, (2) an intermediate layer of ethylene-vinyl acetate and an inner layer (3) of polyethylene or thermoplastic polyurethane elastomer (TPU). In a second embodiment, Donohue describes a co-extruded tubing that includes layers (1) and (3), but not the intermediate layer.

Thus, according to each of Donohue’s embodiments, the inner layer (3) is made of polyethylene. Donohue does not disclose or suggest a tubing that has at least one layer of COPE material, wherein the COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing. Instead, Donohue teaches to employ a polyethylene inner layer (3) which defines the inner surface of the tubing. Accordingly, Donohue does not anticipate the subject matter of claim 32.

Similar comments apply to independent claim 38, which recites a method that includes, among other features, “forming a tubing having at least one layer of the selected copolyester ether (COPE) material, wherein the at least one layer of COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing. Accordingly, Donohue also does not anticipate the subject matter of claim 38.

Furthermore, Donohue does not suggest or render predictable the subject matter of claims 32 and 38. With regard to the inner layer 3, Donohue states that the inner layer provides a fluid-contact surface. (paragraph [0017].) Donohue specifies that the inner layer may be either a polyethylene or a thermoplastic polyurethane elastomer (TPU). Thus, Donohue specifically defines the material for the inner layer 3 for providing a fluid contact surface as being either polyethylene or TPU. Indeed, Donohue specifically teaches to include a co-extruded inner layer (for each of the disclosed embodiments), where the inner layer separates the outer layer (1) from the fluid channel within the tubing and, thus, inhibits the outer layer (1) from defining the inner surface and from contacting any media conveyed within the tubing. Thus, insofar as Donohue's outer layer (1) is a COPE material, Donohue provides no suggestion or motivation for a tubing that has both COPE material defining the tubing outer surface and COPE material defining the tubing inner surface. Such a tubing configuration is contrary and counter-intuitive relative to the express disclosure in Donohue.

The rejection of claims 32 and 38 is, therefore, respectfully traversed.

Claim 2 is amended herein to be in independent form and recites a "tubing for conveying a fluidic media, the tubing comprising an inner layer made of a material compatible with the fluidic media and at least one layer of copolyester ether (COPE) material including an outer layer of COPE defining an outer peripheral surface of the tubing and at least one additional layer of COPE between the outer layer and the inner layer, wherein the material of the inner layer comprises polyethylene or polyurethane."

In contrast to the tubing recited in claim 2, Donohue does not disclose or suggest an outer layer of COPE and at least one additional layer of COPE between the outer layer and the inner layer. Instead, as discussed above, Donohue describes one outer layer (1) that the Examiner identifies as a COPE material. However, there is no disclosure or suggestion in Donohue of providing any additional layer of COPE between that outer layer and the inner layer.

Donohue describes controlling thickness of tubing layers by the extrusion tooling used during the extrusion process (see paragraph [0021]). Thus, Donohue teaches one skilled in the art to define a suitable tubing thickness for the outer tubing layer (1), but does not mention or

suggest providing any additional layers of COPE material between the outer layer (1) and the inner layer (3). Accordingly, the invention recited in amended claim 2 is patentably distinguished over Donohue.

Claims 3-11, 21-25, 27, 29-31, 33, 34, 39 and 45 are each dependent, directly or indirectly, on one of claims 32, 38 and 2. The rejection of those dependent claims is, therefore, respectfully traversed at least for reasons noted above with regard to claims 32, 38 and 2.

Rejections Under 35 U.S.C. 103(a):

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al. in view of U.S. Patent No. 6,248,093 to Moberg. With regard to cancelled claims 15 and 16, this rejection is moot. With regard to claims 12-14 and 17-20, this rejection is respectfully traversed.

Each of claims 12-14 and 17-20 is dependent (indirectly) on claim 32. The rejection of dependent claims 12-14 and 17-20 is, therefore, respectfully traversed at least for reasons noted above with regard to base independent claim 32.

The Moberg reference does not address the above-noted distinctions over Donohue. The Moberg reference was cited by the Examiner for describing a drug delivery system that includes a pump, reservoir and tubing. However, Moberg does not disclose or suggest a tubing having features as discussed above with regard to base independent claim 32. The combination of Moberg with Donohue in the manner suggested by the Examiner, thus, would not result in the invention recited in base, independent claim 32. Accordingly, claims 12-20 are distinguished over the Examiner's suggested combination of Donohue in view of Moberg.

Claims 35-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al. in view of U.S. Patent No. 6,406,767 to Mueller. This rejection is respectfully traversed.

Each of claims 35-37 is dependent (directly or indirectly) on claim 32. Also, each of claims 40-42 is dependent (directly or indirectly) on claim 38. The rejection of dependent claims 35-37 and 40-42 is, therefore, respectfully traversed at least for reasons noted above with regard to base independent claims 32 and 38.

The Mueller reference does not address the above-noted distinctions over Donohue. As discussed above, Donohue does not disclose or suggest a tubing that has at least one layer of COPE material, wherein the COPE material comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing. Instead, Donohue teaches to employ a polyethylene inner layer (3) which defines the inner surface of the tubing. The Mueller reference also fails to disclose or suggest such features.

The Examiner stated that Mueller discloses a tubing wherein the intermediate layer is made of a COPE material (24) that can be co-extruded. According to the Examiner, Mueller's intermediate layer of COPE could replace the intermediate layer of Donohue or be used in addition to the EVA layer (2). While Applicant does not agree with the Examiner's argument that one of ordinary skill in the art would have found it obvious to modify the tubing in Donohue to include an additional COPE layer of Mueller, such a modification still would not meet the invention recited in amended claims 32 and 38 and, thus dependent claims 35-37 and 40-42.

Like Donohue, Mueller also fail to disclose or suggest a tubing having at least one layer of COPE material that comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface defining an inner peripheral surface of the tubing. While Mueller describes an intermediate layer that includes a blend of EVA-based polymeric adhesive and an elatameric copolyester (which can be ECDEL 9965), Mueller neither describes nor suggests a tubing that has both COPE material defining the tubing outer surface and COPE material defining the tubing inner surface. Such a tubing configuration is contrary and counter-intuitive relative to the express disclosure in Mueller. As discussed above, such a tubing configuration is also contrary and counter-intuitive to the express disclosure in Donohue. As neither Mueller nor Donohue disclose or suggest such a configuration, the Examiner's proposed combination of those references would not have led to the invention of claims 32 and 38, and, thus, of dependent claims 35-37 and 40-42. The rejection of claims 35-37 and 40-42 is, therefore, respectfully traversed.

Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al. This rejection is respectfully traversed.

The Examiner stated that Donohue disclose both dual and tri-layer tubing in which COPE comprises the outer layer of the tubing. The Examiner then argues that it would have been obvious to one having ordinary skill in the art to extrude just the COPE into a tube in order to minimize material cost, while taking advantage of the properties of COPE. However, Donohue never mention or suggest forming a tubing with just one layer of COPE and no other layers.

Donohue's focus throughout the disclosure is that of co-extruding layers of multiple materials to form a tubing structure having multiple layers (two or three layers) of different materials. Co-extrusion is referenced by the title, abstract and every embodiment described by Donohue. Donohue teaches to avoid using PVC material by, instead, co-extruding an outer layer of polyester and an inner, fluid-contact layer of polyethylene or a thermoplastic polyurethane elastomer (TPU) to form a tubing. In each embodiment, Donohue includes an inner, fluid-contact layer, that is different from the outer layer. Had a single or multiple layer COPE tubing (with no further inner layer) been contemplated or obvious, Donohue would have made some mention of that alternative.

However, instead, Donohue's teaching is to co-extrude a separate, inner layer of polyethylene or TPU (that is a different layer and a different material from the outer layer). Furthermore, Donohue's focus on co-extrusion processes would lead one skilled in the art away from a single-layer configuration. Note that Donohue's title, abstract and detailed description focus on co-extrusion as a procedure for making their tubing structure (where co-extrusion involves forming two or more layers, at the same time). One of ordinary skill in the art would read Donohue as teaching of co-extrusion of multiple materials. One of ordinary skill in the art would not read Donohue as suggesting a tubing having only COPE layers, or having a single layer of COPE and is free of other layers. Accordingly, the rejection of dependent claims 43 and 44 is further respectfully traversed.

New Claims:

New claim 46 is added and is dependent on claim 32. Accordingly, new claim 46 is allowable over the references of record, at least for reasons as discussed above with respect to claim 32. In addition, new claim 46 is further distinguished from the references of record. For

example, new claim 46 recites that “the inner surface is coated with a material for enhancing compatibility with the fluidic media.” Such features are supported by the original disclosure, for example, but not limited to paragraph [0037].

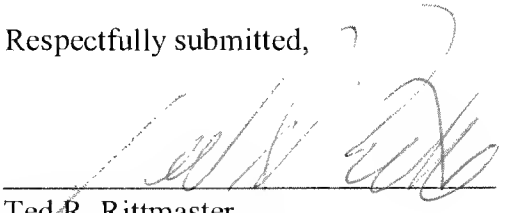
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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